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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/565,214 | 01/20/2006 | Frank Pfluecker | MERCK3116 | 9757 |
| 23599 7590 02/03/2009 MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. | | | EXAMINER | |
| | | | NGUYEN, COLETTE B | |
| SUITE 1400 ARLINGTON, VA 22201 | | | ART UNIT | PAPER NUMBER |
| | | | 1793 | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | Application No. | Applicant(s) | | | | |
|--|---|--|-----------------------|--|--|--|--|
| Office Action Summary | | 10/565,214 | PFLUECKER ET AL. | | | | |
| | | Examiner | Art Unit | | | | |
| | | COLETTE NGUYEN | 1793 | | | | |
| Period fo | The MAILING DATE of this communication app or Reply | pears on the cover sheet with the c | orrespondence address | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | | |
| Status | | | | | | | |
| 1)[\ | Responsive to communication(s) filed on <u>10/2</u> : | 7/08 | | | | | |
| · · | | action is non-final. | | | | | |
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| ٥,١ | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Dispositi | ion of Claims | | | | | | |
| · · | | the application | | | | | |
| • | Claim(s) <u>1-5,13-21,28 and 29</u> is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | |
| | | | | | | | |
| · — | 5) Claim(s) is/are allowed. | | | | | | |
| · · | 6) Claim(s) <u>1-5,13,21,28 and 29</u> is/are rejected. | | | | | | |
| • | Claim(s) is/are objected to. Claim(s) are subject to restriction and/o | r cleation requirement | | | | | |
| ا (۵ | are subject to restriction and/o | r election requirement. | | | | | |
| Applicati | on Papers | | | | | | |
| • | The specification is objected to by the Examine | | | | | | |
| 10) | The drawing(s) filed on is/are: a)☐ acc | epted or b) \square objected to by the ${	t E}$ | Examiner. | | | | |
| | Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | | |
| Priority ι | ınder 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some col None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | |
| 2) Notic 3) Inform | e of References Cited (PTO-892) se of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other: | ate | | | | |

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DETAILED ACTION

Status of the Application

Claims 1-22, 25-27 have been amended, 23, 24 cancelled, 28 and 29 are new. They are pending and presented for examination.

Election/Restrictions

- 1. On June 9th, 2008, applicant's attorney, Mr. Brian Heaney made a provisional selection with traverse of Group 1, claims 1-5 and 13-21. However, in the amendment filed on October 27, 2008, applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, therefore the election has been treated as an election without traverse (MPEP § 818.03(a)).
- 2. This application contains claims 6-12, 22, 25-27 drawn to an invention nonelected with traverse in the reply filed on October 27,2008. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.
- 3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 5. Claims 1-5, 13-22, 28 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 6. In Claim 1, the word "obtainable" is unclear as to whether the claim is limited to one made the claimed method or merely preferably made by the claimed method. The metes and bounds of the claim are not clearly defined. For purposes of examination, the claim is interpreted as a product-by-process claim in which the product is made by the claimed treatment and application of coating.

Claim Rejections - 35 USC § 103

- 7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.
 - 2. Ascertaining the differences between the prior art and the claims at issue.
 - 3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

- 9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 10. <u>Claims 1-17,19-22 and 25-29</u> are rejected under 35 U.S.C. 103(a) as being unpatentable over Schumacher et al (6,773,814) in view of Bruno (5,776,239).
- 11. Regarding claim 1. Schumacher et al (814). Schumacher et al. teaches a metal oxide particles coated with silicon dioxide, in particularly the titanium oxide, widely used in sun screening agent. The metal oxide is obtained by using hydrothermal process (Schumacher, Col.2, In9-13). He does not specify the temperature range of the process. Bruno,(239) discloses a process to make an ultrafine titanium dioxide powder, having an average crystalline size of 1-100nm, used in cosmetic and other applications for controlling exposure to ultraviolet (UV) light. The process is a hydrothermal heat treatment process in a sealed pressure vessel at a temperature range of 200-250C. (Bruno, Col.2, In40-50, col6, In.59-66, col.7, In. 1-5). The process provides uniform ultrafine particle. The process can also be employed for coating inorganic metal oxide upon a wide range of core particles, including TiO₂ and these core particles can include a

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plurality of coatings, including SiO₂. (Bruno, col. 2, ln 40-48). It would have been a good motivation for one of ordinary skill in the art to combine both teachings of Schumacher and Bruno as both disclose method of making nano-particulate UV protectant which has a silicon dioxide coating by hydrothermal treatment in a closed container at an elevated temperature range to speed up the formation of the nano-particles with uniformity in size. As Bruno's temperature range is 200-250C, which is within the claimed range temperature of 140-360C, it would have been obvious for one of ordinary skill in the art at the time of the invention to use a temperature as taught by Bruno to perform the hydrothermal process in the method of Schumacher et al.

- 12. Regarding claim 2. Schumacher in view of Bruno disclose a nano-particulate UV protectant according to claim 1. Bruno discloses an option of doping with metals as doping metals can cause a reduction in the particle size of ultrafine metal oxides.

 (Bruno, Col2, In5-9 andCol.6, In 30-35)
- 13. Regarding claim 3. Schumacher in view of Bruno disclose a nano-particulate UV protectant according to claim 1 wherein the nano-particulate metal oxide have a crystallite size of 1-100nm. (Bruno, col.4, In59-61).
- 14. Regarding claim 4. Schumacher in view of Bruno disclose a nano-particulate UV protectant according to claim 1 Schumacher teaches a thickness of silicon dioxide coating, expressed in nanometer of between 0.5 and 25 nm as compared to the metal oxide size of 2 to 100nm. In percentage, it is equivalent to 20%, based on the size of the metal oxide plus the thickness of the silicon dioxide. It is inherent for the particle to have a percent weight range similar as the claimed range of 5 to 50% by weight as the

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claimed products and cited reference prior arts products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical process, a prima facie case of either anticipation or obviousness has been established. See I MPEP 2144.06. In *re. Toro Co. vs Deere Co. 69USPQ2d* on Inherency. (Schumacher, Col2, line 50-67).

- 14. Regarding claim 5. Schumacher in view of Bruno disclose a nano-particulate UV protectant according to claim 1. Schumacher teaches a coated metal oxide particle with a dimension range of 2-100nm, preferably between 5-50nm. The dimensions of the coated metal oxide under a transmission electron microscope are inherent in the X- Ray diffraction range (Scherrer method is a X-Ray diffraction) of the particle, therefore the dimensions of the particle in the instant claim are already anticipated by Schumacher's teaching for the coated metal oxide particle (Col 2, line 51-55).
- 15. Regarding claims 13, 14, 15, and 17. Schumacher in view of Bruno disclose a composition having light protection according to claim 1 by specifically mentioning the applications of the silica-coated metal oxide powder not only in cosmetics but also widely to known inorganic UV-absorbing pigments used in coating, fiber or film, suncreens (light protection) in the form of lotions, creams, mousses, milk sprays (dermatological formulation) and other personal care products also can be applied. (SchumacherCol4, line 17-20, Col 5, line 1-10) and (Bruno, Col 7, In27-30 and In 62-64).
- 16. Regarding claim 18. Schumacher in view of Bruno disclose a nanoparticulate UV protectant according to claim 1 wherein a photostabilizer is used as an additive with the

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coated metal oxide in UV protection(Schumacher, Col 4, In 55-65 "benzophenones and benzimidazole and benzylidene camphor and their derivatives). The claimed formula is a benzylidene derivative. it would have been obvious for one of ordinary skill in the art at the time of the invention to choose the claimed formula through process optimization, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranged or known derivatives involves only routine skill in the art. See *In re Boesch*, 205 USPQ 215 (CCPAP1980).

- 17. Regarding claims 16,19, 20, 21. Schumacher in view of Bruno disclose a composition having light protection according to claim 1 wherein the silica-coated metal oxide in sunscreen agents (light and UV protection) also have chemical UV filters. The UV filters can be water or oil soluble such as sulphonic acid derivatives of benzophenones and benzimidazole derivatives of dibenzoylmethane. Benzylidene camphor and their derivatives, derivatives of cinnamic acid and their esters, or esters of salicylic acid (Schumacher,Col 4,line 43-68). Furthermore, other substances such as vitamins, antioxidants, preservatives, colorants and perfumes also can be combined with the coated metal oxide particle as mentioned. (Schumacher,Col.5, line 1-15).
- 18. Regarding claim 28. Schumacher in view of Bruno disclose a nano-particulate UV protectant according to claim 1, wherein the metal oxide is titanium dioxide doped with iron. (Bruno, Col 2, In 5-9).
- 19. Regarding claim 29. Schumacher in view of Bruno disclose a nano-partriculate UV protectant according to claim 1. wherein the hydrothermal treatment is carried in a

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closed container at a temperature of 200-250C (Bruno, Col 7, In5-7). As the disclosed temperature range of 200-250C is within the claimed temperature of 150-360C. an overlapped range exists, therefore a prima facie case of obviousness exists. See MPEP 2144.05. It would have been obvious for one of ordinary skill in the art at the time of the invention to use process optimization to speed up the process by increasing the temperature as Bruno discloses that a sealed vessel has to be used therefore volatile products can be contained.

Response to Arguments

15. Applicant's arguments with respect to claim1-5,13-21 have been considered but are most in view of the new ground(s) of rejection.

Response to Amendment

16. The Declaration under 37 CFR 1.132 filed on October 27th, 2008 is insufficient to overcome the rejection of claim1-5, 13-21 because: (1) The evidence is non commensurate in scope with the claimed invention. The photoactivity test only shows difference between 105C and 180C, not the claimed range 140 to 360C. The UV A absorption is not clear as to whether the difference between 105C and 150C is significant and is not commensurate in scope with the claimed range of 140 to 360C. (2) As taught by Bruno, hydrothermal treatment is performed at 200-250C, within the claimed range of 140 to 360C.

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Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US6,500,415 and US 6,235,270.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to COLETTE NGUYEN whose telephone number is (571)270-5831. The examiner can normally be reached on Monday-Thursday, 10:00-4:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Curt Mayes can be reached on (571)-272-1234. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/COLETTE NGUYEN/ Examiner, Art Unit 1793

CN February 1, 2009

/Melvin Curtis Mayes/ Supervisory Patent Examiner, Art Unit 1793